

### REMARKS

Claims 1-14, 16-22 and 24 and 25 are pending in the present application. By virtue of this response, claims 1, 11 and 22 have been amended, no claims have been cancelled and no new claims have been added. Accordingly, claims 1-14, 16-22 and 24 and 25 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

#### **Rejection of claims under 35 U.S.C. 102(e)**

A. Claims 1, 11 and 16 stand rejected under 35 U.S.C 102(e) as allegedly being anticipated by U.S. Patent 6,143,019 to Motamedi et al (“Motamedi”). In support of this rejection, the Office Action (Paper Number 17) states the following on page 2:

Motamedi et al teaches a method for cardiac tissue ablation (lesion) using light activated substances with photodynamic therapy (Col. 6, lines 3-7) for modification of tissues responsible for cardiac arrhythmias (abstract). Photodynamic procedures inherently use non-thermal light in the process. All light sources, including a single source, produce light in a predetermined pattern that will produce a predetermined result on sensitized tissue. The light pattern is inextricably related to the light pattern.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP §2131).

Motamedi et al. generally describes ablating cardiac tissue in a *diffuse* manner. See Motamedi, Abstract and col. 2 line 39-44: “The present invention address the problem described above by (1) delivering laser light or other ablating energy intramyocardially, *and (2) diffusing the ablating energy over a broad area in the myocardium* without causing excess heat on the endocardial surface or in the blood pool” [emphasis added]. See also, column 9, lines 46-51 (“...light does not exit from the distal end of the tip 42, but *diffuses laterally into a broad area of myocardium* (FIG. 4).” [emphasis added]), column 2, lines 52-55 (“The present invention thus provides instruments and methods for percutaneous catheter ablation of larger myocardial lesions

than have previously been possible, by the intramyocardial *delivery of diffused laser light*” [emphasis added]). Thus Motamedi describes delivering light energy diffusely to ablate a large volume of tissue.

In contrast, Applicant’s independent claims 1 and 11 recite a method of producing predetermined *patterned* lesions in cardiac tissue by having the light source arranged so as to produce a lesion in a pattern corresponding to the light source such that non-target tissue is not exposed to the light. Motamedi describes diffused light, and does not describe making patterned lesions. In particular, Motamedi does not describe creating a predetermined pattern corresponding to the light source such that non-target tissue is not exposed to the light.

The Office Action fails to recognize the distinction between a patterned lesion and lesion created by diffused light. The Office Action asserts that “[a]ll light sources, including a single source, produce light in a predetermined pattern that will produce a predetermined result on sensitized tissue” (Paper 17, page 2). Applicant strongly disagrees with this statement. Patterns arise by controlling where light does *and does not* reach. For example, the *diffuse* light described by Motamedi does not make a predetermined lesion pattern because Motamedi does not protect non-target tissue.

Therefore, for at least the reasons above, independent claims 1 and 11 are patentable over Motamedi. Dependent claim 16, which ultimately depends therefrom, is also patentable for at least the same reasons. Accordingly, Applicant respectfully request the reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e).

**B.** Claims 1-5, 11-14 and 16 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent Publication 20002/0095197 to Lardo et al. (“Lardo”). In support of this rejection, the Office Action (Paper Number 17) states the following on page 3:

Lardo teaches a non-thermal method for the treatment of cardiac arrhythmia (Paragraph 0011) using a photosensitizing agent (Paragraph 0012) and illumination by a fiber-optic catheter that may be arranged in a linear or ring-shaped pattern (Paragraph 0015) to produce well-defined patterns of cardiac ablation (Paragraph 0035). Lardo teaches the

ectopic foci of the pulmonary veins as target areas (Paragraph 0007). The photosensitizing agent may be delivered systemically or locally (Paragraph 0016).

Applicant believes that Lardo is only available as potential 102(e) art as of July 11, 2000. Lardo was filed July 11, 2001, but claims priority to a provisional application No. 60/217,522 filed July 11, 2000. The present application claims priority to July 31, 2000. Accompanying this response is a declaration under 37 C.F.R. §1.131 by Inventor Benjamin D. Pless, a declaration under 37 C.F.R. §1.131 by patent attorney E. Thomas Wheelock, and three exhibits. The Pless and Wheelock declarations indicate that the invention of claims 1-5, 11-14 and 16 was conceived prior to July 11, 2000 and constructively reduced to practice by the filing of the patent application on July 31, 2000, including the use of a photosensitizing agent and illumination by a light source to produce well-defined patterns of cardiac ablation, using ectopic foci of the pulmonary veins as target areas, and the systemically or local delivery of photosynthesizing agents.

Accordingly, Lardo et al. is not available as a reference under 102(e). In view of this, Applicant respectfully requests withdrawal of this rejection.

C. Claims 22 and 24 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent 6,443,974 to Oron et al ("Oron"). In support of the rejection of claims 22 and 24, the Office Action (Paper No. 17) states the following on page 3:

Oron discloses a catheter for biostimulation of cardiac tissue using electromagnetic radiation that may be visible light (abstract). The light emitting area is disclosed as being flexible with the radiating element in a cutaway section (window) and a lens for emitting the beam in an outward radial direction (Col. 22, lines 42-52). The radiating area is surrounded by the catheter body (opaque) and is linear for a length of 2-3 cm (Col. 22, line 56). The radiating area inherently emits substantially all of the light from the device due to the catheter blocking radiation in other directions and a reflecting coating on the inner surface (Col. 22, line 53).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP §2131).

Oron describes an apparatus for electromagnetically stimulating cardiac tissue containing a radiation emitting element. (See Oron, Col. 22, lines 43-62). Oron shows and describes emitting radiation only from the entire surface of the radiation emitting element.

In contrast, independent claim 22 recites a linear light emitting region wherein a portion of the linear light emitting region can be selectively illuminated. Because Oron does not show or describe every element of claim 22, Oron cannot anticipate independent claim 22.

Therefore, for at least the reasons above, independent claim 22 is patentable over Oron. Dependent claim 24, which ultimately depends therefrom, is also patentable for at least the same reasons. Accordingly, Applicant respectfully request the reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(e).

#### **Rejection of claims under 35 U.S.C. 103(a)**

A. Claims 6-10 and 17-21 stand rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over U.S. Patent Publication 20002/0095197 to Lardo et al. as applied to claims 1 and 11 and further in view of U.S. Patent 6,164,283 to Lesh.

As discussed above, Lardo is not available as prior art under 102(e). Consequently, the Office Action fails to set for a *prima facie* case of obviousness. Accordingly, Applicant respectfully requests that the rejection of claims 6-10 and 17-21 under 35 U.S.C. §103(a) be withdrawn for at least the reasons described above.

B. Claim 25 stands rejected under 35 U.S.C. 103(a) allegedly as being unpatentable over U.S. Patent 6,443,974 to Oron et al.

In support of the rejection of claim 25, the Office Action (Paper No. 17) states the following on page 5:

Oron is discussed above but does not disclose LED's as a light source. The use of LED's is well known in the art and therefore it would have been obvious to use LED's in the device of Oron as a viable light source.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. (MPEP §2143.)

As discussed above, Oron fails to teach or suggest all the claim limitations of independent claim 22, from which claim 25 depends. Further, there is no suggestion or motivation to modify the reference to incorporate all of the claim limitations, and there would be no reasonable expectation of success upon doing so. Consequently, the Office Action fails to set forth even a *prima facie* case of obviousness. See MPEP §2143.

Accordingly, Applicant respectfully requests that the rejection of claim 25 under 35 U.S.C. §103(a) be withdrawn for at least the reasons described above.

## CONCLUSION

Applicant has, by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in the outstanding Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 473912000100. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated:

5/7/04

Respectfully submitted,

By

Rick Shoop

Registration No.: 45,763

MORRISON &amp; FOERSTER LLP

755 Page Mill Road

Palo Alto, California 94304

(650) 813-5804